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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,266	05/03/2000	THOMAS HILLE	FLA-0035	3529

7590 05/20/2003

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/20/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/486,266

Applicant(s)

HILLE ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-33,35-39,42-49,53-55 and 57-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33,35-39,42-49,53-55 and 57-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment E, filed 02/19/2003.

Claim 41 has been canceled per applicants' amendment E. Claims 22-33, 35-39, 42-49, 53-55, 57-68 are pending in the application.

The standing rejections:

Specification

1. The disclosure is objected to because of the following informalities: in page 8, line 9, there is a typographical error. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

2. Claims 22-33, 35-39, 42-49, 53-55, and 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,390,520 ('520), or US 5,225,199 ('199) each by itself or US '520 in combination with US '199.

US '520 discloses a transdermal analgesic adhesive comprising a pressure sensitive adhesive layer containing the drug and a flexible substrate (backing). The backing expands on one direction and prepared from polyethylene and having a moisture permeability from 5 to 2000 g/m²/hr. The adhesive layer comprises vinyl pyrrolidone (abstract; col.2, lines 49-68; col.3, lines 1-2, 55-56).

US '199 teaches a pharmaceutical plaster comprising film layer (represents the backing), adhesive layer containing the drug such as hormone or buprenorphine, and another covering layer removed before use. The film layer has elongation (elasticity) of 30 to 150 % and made of polyethylene terephthalate (abstract; col.3, lines 58-61; col.5, lines 34-35).

No superior and unexpected results were established showing the criticality of the claimed ranges of wrap thread and weft thread. It is within the skill in the art to have differentiated marking elements.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver transdermal therapeutic system comprising adhesive reservoir layer containing the active ingredient; a release liner; and a uni-directional elastic backing disclosed by US '520 and adjusting the elasticity of the backing to that percentage disclosed by US '199, motivated by the teaching of US '520 and US '199 that the elasticity of the backing prevents the sense of tension from the skin, with reasonable expectation of success of delivering a comfortable patch.

Response to Arguments

3. Applicant's arguments filed 08/29/2002 have been fully considered but they are not persuasive.

Applicants argue that:

- US '520 does not teach flexible substrate that prevents the disagreeable sense of tension. The reference teaches vinyl pyrrolidone monomer within acrylic acid copolymer and not as a water-absorbing polymer.
- Regarding US '199 does not teach water absorbable polymer such as polyvinyl pyrrolidone.
- The present claim 22 is neither disclosed nor made obvious to the skilled artisan at the time the present invention was made.

In response to the above argument, the examiner position is:

- The present claims are product claims and all the element of the product are disclosed by the US '520, i.e. flexible backing having unidirectional elasticity, an adhesive layer comprising active agent, and copolymer containing polyvinyl pyrrolidone. The future intended use does not impart patentability to composition claims. The expression "comprising" of the claim language permits the presence of the copolymers of poly vinyl pyrrolidone.

- US '199 teaches the polyvinyl pyrrolidone, col.14, line 63, and water absorption is a property of particular polymer.
- The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '199 suggests the amount of elasticity and US '520 suggests the unidirectional elasticity. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal therapeutic system comprising a unidirectional elastic backing as disclosed by US '520 and adjusting the elasticity of the backing to that percentage disclosed by US '199 and replace the copolymer comprising polyvinyl pyrrolidone by the poly vinyl pyrrolidone as disclosed by US '199, motivated by the teaching of US '520 and US '199 that the elasticity of the backing prevents the sense of tension from the skin, and motivated by the teaching of US '199 that poly vinyl pyrrolidone acts as a diffusion auxiliary, with reasonable expectation of success of delivering a comfortable patch with reasonable diffusion.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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